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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BRADLEY, CHRISTINA	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,822	ARBIT ET AL.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *59-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 59-131 are pending.

Claim Rejections - 35 USC § 112

2. The rejection of claims 59-78, 88-101, 106, 108-116 and 119-131 under 35 U.S.C. 112, first paragraph, is withdrawn in light of the amendment to the claims filed 2/08/2008.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 59-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Weidner *et al.* (WO 02/02509). Weidner *et al.* teach a solid oral delivery capsule comprising zinc human recombinant insulin and 4-[(4-chloro, 2-hydrozybenzoyl)amino]butanoic acid and a method of administering the composition to diabetic monkeys (see Example 1g on page 20 for capsule preparation and Example 2 on pages 22-24 for delivery), satisfying the structural limitations of claims 59-72, and 76-89. Regarding claims 73-75, the dose of insulin is 0.25-0.5 mg insulin/kg of monkey. The monkeys ranged in weight from 2-3 kg. Thus, the total dose of insulin was 0.75-1.5 mg, which is about 2, 3.8 and 5.75 mg. Regarding claims 90 and 91, the dose of 4-[(4-chloro, 2-hydrozybenzoyl)amino]butanoic acid is 25, 50 or 100 mg/kg of bodyweight. Thus the total dose was 50-300 mg of 4-[(4-chloro, 2-hydrozybenzoyl)amino]butanoic acid which falls

within the range in claims 90 and 91. Weidner *et al.* do not teach that the oral dosage form of insulin results in the specific effects of administration in diabetic humans recited in claims 59-62, 64-69, 76-78 or 85-89. Because the chemical structure of the oral solid dosage form of insulin taught by Weidner *et al.* is identical to the claimed invention, Weidner *et al.* inherently teaches the claimed functional limitations.

5. In traverse of the rejection, Applicant argues that there is not a reasonable expectation that the solid oral delivery capsule disclosed in Weidner *et al.* would necessarily meet the additional functional limitations as claimed. Specifically, Applicant argues that the oral dosage form taught by Weidner *et al.* would not necessarily achieve a therapeutically effective reduction in blood glucose after oral administration to a human diabetic patient as compared to an untreated diabetic patient. This argument is unpersuasive because the prior art composition is physically identical to the claimed invention and therefore must possess identical functional characteristics. MPEP § 2112.01 states: "If the composition is physically the same, it must have the same functional properties. 'Products of identical chemical composition can not have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)" In the instant case, the prior art reference teaches an oral dosage formulation comprising a dose of unmodified insulin and an amount of a delivery agent 4-CNAB. Thus, the prior art dosage form is physically identical to the claimed dosage form and therefore necessarily possesses the identical functional properties.

6. Applicant goes on to argue that Weidner *et al.* fail to provide sufficient evidence to show that the specific claimed effects would necessarily result from oral administration to diabetic humans of the oral dosage form of Weidner *et al.* In support of this position, Applicant notes that the animal studies described in Weidner *et al.* were not performed on diabetic animals or even on animals with impaired glucose tolerance, and that Weidner *et al.* did not disclose any analysis of administration of the composition to any other animal subjects or suggest the suitability of the composition for the administration to diabetic humans. MPEP § 2112 states that the "discovery and characterization of properties of a known material do not make it novel." Applicant's discovery that the claimed composition can achieve a therapeutically effective reduction in blood glucose after oral administration to a human diabetic patient does not distinguish the invention over the prior art of Weidner *et al.* which teaches that the physically identical composition lowers blood glucose levels in non-diabetic animals. Applicant argues that the reference is silent as to the effects of such administration upon diabetic animals and is silent as to the comparative effects of the composition on diabetic rats or monkeys. This argument is not persuasive because it is not necessary for the prior art to explicitly teach all functional effects of a claimed composition in order to anticipate the claim. MPEP § 2112 states "Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference." In the instant case, the functional effects of the composition are a property that is inherent to its physical structure. Because the compositions of the prior art and the claims are identical, the functional effects are identical. Claims 59-91 are drawn to

compositions, not to methods. Therefore, the fact that Weidner *et al.* is silent as to administration of the composition to diabetic humans is insufficient to overcome the rejection.

7. Applicant goes on to argue that there is no reasonable expectation that the composition disclosed in Weidner *et al.* would inherently teach the functional limitations of the claims, that the prior art reference fails to provide sufficient basis in fact or technical reasoning to support the determination, and fails to make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that the case for inherency has been established by probabilities or possibilities. This is unpersuasive. The technical reasoning that the functional limitations are inherent to the teaching in the prior art is that the composition in the prior art is physically identical to the composition in the claims and therefore must possess identical functional properties. Applicant has presented no evidence that a composition that is structurally identical to the claimed composition could fail to possess identical functional properties.

8. Applicant goes on to argue that the case of inherency is merely an invitation to investigate and that the prior art reference discloses no more than a broad genus of potential applications of its discoveries. Specifically, Applicant argues that the prior art reference merely invites further experimentation to find out how the described oral solid dosage form would perform when administered to diabetic humans in comparison to non-treated diabetic human subjects. This is unpersuasive. Claims 59-91 are drawn to compositions, not to methods. Therefore, the fact that Weidner *et al.* is silent as to administration of the composition to diabetic humans is insufficient to overcome the rejection.

9. Finally, Applicant argues that the prior art reference must be sufficiently described and enabled in order to anticipate the claims and that in the instant case, the prior art composition of

Weidner *et al.* is not enabled for administration to diabetic humans. Applicants present a declaration from Dr. Shingai Majura which argues that it would require undue experimentation for one of skill in the art to determine how a particular composition would perform when administered to diabetic human subjects in comparison to untreated human subjects based upon knowledge of how the composition performs when administered to non-diabetic animal subjects. This is unpersuasive. The prior art is replete with examples of the treatment of diabetic humans with insulin compositions. Drawing on the knowledge of the art and the guidance presented in the Weidner *et al.* reference, the skilled artisan could, through routine experimentation, adapt the composition for administration to diabetic humans.

10. For these reasons, the rejection of claims 59-91 is maintained.

Claim Rejections - 35 USC § 103

11. The rejection of claims 92-131 under 35 U.S.C. 103(a) as being unpatentable over Weidner *et al.* (WO 02/02509) is withdrawn. Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as WO 02/02509 at the time this invention was made. Therefore, reference WO 02/02509 is disqualified as prior art under 35 U.S.C. 103(c).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

13. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

14. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 92-131 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29, 33-38 and 40-59 of copending Application No. 10/541,433. Although the conflicting claims are not identical, they are not patentably distinct from each other. Specifically, claims 6 and 11 of copending Application No. 10/541,433 recite a method of administering an oral solid formulation of insulin and 4-CNAB (4-[(4-chloro, 2-hydrozybenzoyl)amino]butanoic acid) (claim 11) to human diabetics (claim 6) at bedtime. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 59-131 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-92 of copending Application No. 11/072,941. Although the conflicting claims are not identical, they are not patentably distinct from each other. Specifically, copending Application No. 11/072,941 claims 65 and 74 each recite an oral tablet formulation of insulin and (4-[(4-chloro, 2-hydrozybenzoyl)amino]butanoic acid. Copending Application No. 11/072,941 claims 83 and 87 recite a method of administering this composition to diabetics. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 59-131 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-39, 42-45, 50, and 55-63 of copending Application No. 11/204,778. Although the conflicting claims are not identical, they are not patentably distinct from each other. Specifically, copending Application No. 11/204,778 claims 42 and 45 each recite an oral tablet formulation of insulin and (4-[(4-chloro, 2-hydrozybenzoyl)amino]butanoic acid. Copending Application No. 11/204,778 claims 57-63 recite a method of administering this composition to diabetics. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No claims are allowed.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 9:00 A.M. to 3:30 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654